AMO
ADVANCED MEDICAL OPTICS

FEB 1 2 2003

510(k) SUMMARY

K024106

COMPLETE® brand Multi-Purpose Solution

This summary uses the format provided in 21 CFR 807.92:

(a)(1) **Submitter:**

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Summary Prepared: December 16, 2002

(a)(2) **Device Trade Name:** COMPLETE® brand Multi-Purpose Solution

Device Common Name: Soft (Hydrophilic) Contact Lens Solution

Device Classification/Panel: Class II (Special Controls)/Ophthalmic Device

Device Classification Names: Accessories to Contact Lens Solution (86LPN)

(a)(3) **Identification of Predicate Device:** When used as directed, COMPLETE® brand Multi-Purpose Solution is substantially equivalent to the currently marketed product.

(a)(4) **Device Description:** COMPLETE® brand Multi-Purpose Solution is a sterile, isotonic, buffered, solution containing lubricants, preservatives, buffers, surfactants, ancillary ingredients, and purified water.

The product is a clear, colorless solution packaged in plastic bottles with controlled dropper tips.

(a)(5) **Intended Use (Indications for Use):** COMPLETE® brand Multi-Purpose Solution is used for chemical disinfection, cleaning, rinsing, storing, protein removal and conditioning of soft (hydrophilic) contact lenses. There are no changes to the indications for use.

(a)(6) **Comparison of Technological Characteristics:** The technological characteristics of the product remain the same.

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COMPLETE® brand Multi-Purpose Solution
December 16, 2002

(b)(1) **Discussion of Nonclinical:**

Passive Protein Cleaning: COMPLETE® brand Multi-Purpose Solution and a marketed multipurpose solution were tested for their abilities to remove lysozyme protein adsorbed to contact lens surfaces and within the lens matrix. COMPLETE® has statistically significant better passive protein cleaning ability than the marketed competitor's product.

Microbiological Studies: COMPLETE® was evaluated for microbiological efficacy using studies outlined in FDA's Premarket Notification [510(k)] Guidance Document for Contact Lens Care Products, issued May 1, 1997. The product meets current FDA requirements for disinfection of contact lenses against bacteria, yeast and mold.

(b)(2) **Clinical:**

Clinical safety and acceptability of COMPLETE® brand Multi-Purpose Solution was established in a prior file. Passive protein cleaning and microbiological testing included in this application demonstrate the effectiveness COMPLETE® brand Multi-Purpose Solution when used as directed.

(b)(3) **Conclusions Drawn from Data Supporting Equivalence Determination:** The safety, efficacy and performance of reformulated COMPLETE® brand Multi-Purpose Solution, when used as directed, is substantially equivalent to other contact lens care multi-purpose solutions currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 2003

Paul J. Nowacki
Manager, Regulatory Affairs
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P.O. Box 25162
Santa Ana, CA 92799-5162

Re: K024166
Trade/Device Name: COMPLETE® brand Multi-Purpose Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) contact lens care products
Regulatory Class: Class II
Product Code: LPN
Dated: December 16, 2002
Received: December 17, 2002

Dear Mr. Nowacki:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER:
(IF KNOWN): K024166

DEVICE NAME: COMPLETE® brand Multi-Purpose Solution

INDICATIONS FOR USE:

COMPLETE® brand Multi-Purpose Solution is indicated for the care of soft (hydrophilic) contact lenses. Use this product, as recommended by your eye care practitioner, to:

- Chemically (NOT HEAT) Disinfect
- Clean
- Rinse
- Store
- Remove Protein
- Condition

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter-Use JS
(Per 21 CFR 801.109 Karen Warburton (Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K024166